

Appl. No.: 10/053,329
Amendment dated June 21, 2005
Reply to Office Action mailed January 25, 2005

REMARKS

The Office Action of January 25, 2005 has been carefully reviewed and these remarks are responsive thereto.

Claims 80-86 and 88-107 are pending. Claims 1-79 and 110-135 are withdrawn. Claims 87-88 and 108-109 are cancelled. The Office Action objected to the drawings as failing to show all the features recited in the claim 85. The Office Action rejected claims 80-102 under 35 U.S.C. § 112, ¶ 1 as failing to comply with the written description requirement. The Office Action also objected to the specification as failing to provide proper antecedent basis for the claimed subject matter with regards to claims 95-98. The Office Action rejected claims 80-83, 85-89, 103, 107-109 under 35 U.S.C. § 102(e) as being anticipated by U.S. Publication No. 2003/0069541 to Gillis *et al.* ("Gillis"). The Office Action rejected claim 80-81, 83-90, 103, and 107-109 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,129,685 to Howard, III ("Howard"). The Office Action rejected claims 82-84, 91-102 and 104-106 under 35 U.S.C. § 103(a) as being unpatentable over Howard in view of U.S. Patent No. 5,111,316 to Elsberry *et al.* ("Elsberry").

In response, Applicants respectfully traverse the rejection with the following remarks.

Restriction Requirement

During a telephone call, the Examiner indicated that the claims 80-135 were subject to a four way restriction requirement, dividing the claims into Group I (claims 80-109), Group II (claims 110-113 and 120-135), Group III (claims 114-117) and Group IV (claims 118-119). During the telephone call, Group I was provisionally elected. As requested by the Office Action, Applicants confirm their election of Group I (claims 80-109). This election is made without traverse. The Applicants' election is without prejudice or admission with respect to the Applicants' right to re-file the withdrawn claims in a divisional application.

Informality

Claims 80, 102 and 103 have been amended to clarify the antecedent basis for the use of term "cannula." Pursuant to normal patent practice, an "a" has been inserted in front of first use

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of the term "cannula." Where the open ended phrase "comprising" is used, it should not be construed as a suggestion that the amended claims are limited to a single "cannula."

Amendments to the Claims

As noted above, claims 80, 102 and 103 have been amended.

Claims 86 and 107 have also been amended. It is respectfully submitted that, as discussed in greater detail below, the terminology used in the amended claims 86 and 107 comports more closely with the terminology used in the detailed description. However, as support for this terminology is at least found on line 10 of page 19 of the specification as filed, no new matter has been added.

Objections to the Drawings

The Office Action objected to the drawings because they fail to show a "cannula having plural openings in the lumen distal end with the first and second catheters protruding as claim in claim [80]." Applicants respectfully disagree. Page 4 of the specification describes the therapy delivery element of an exemplary embodiment as being a catheter, and page 11 of the specification discusses FIGS. 4-7 and explains that the leads could provide drug delivery (e.g., constitute catheters). FIG. 8 provides an example of how the leads could be configured with a cannula and is provided with openings 815-818. Accordingly, Applicants believe examples of all the elements recited in the claims are shown in the provided figures. However, to address the Examiner's concerns, a paragraph on page 12 of the specification has been amended to clarify what is shown in FIG. 8. No new matter has been introduced by this amendment.

Regarding the alleged failure to show a first and second port connecting the first and second catheter to the delivery device 10A, FIG. 11 depicts an exemplary port 20A connected to a delivery element 23 that terminates near the distal end 115. The discussion with regards to FIGS. 4-8 explains that multiple leads, which can be catheters, are bundled together and that such leads can be used to deliver medication according to FIG. 11. Therefore, Applicants respectfully submit that the requirements of 37 C.F.R. 1.83 are met with the existing drawings.

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Rejection under 35 U.S.C. § 112, ¶ 1

The Office Action rejected claims 80-102 under 35 U.S.C. § 112, ¶ 1 for failing to meet the written description requirement. The Applicants note that it is not clear whether claims 103-109 are also rejected, however, to the extent these claims are rejected, the following discussion applies equally to them. As an initial matter, the Applicants submit that the claims are fully supported with sufficient written description by the original disclosure (including the claims) of the parent application. Moreover, as the specification makes clear, the disclosed teachings may be implemented within either an electrical stimulation system or a drug delivery system. As a result, the specification utilizes the term "therapy delivery device" to refer generally to either a signal generator or a pump and a "therapy delivery element" to refer generally to either an electrode or a catheter. As detailed below, the Applicants submit that each of the claimed features is supported by an adequate written description.

As noted above with respect to the FIGS. 4-8, examples of leads depicting all the limitations of claim 80 are provided on page 11 of the specification as filed. Furthermore, the use of ports to connect the leads to the delivery device is also referred to on page 11 of the specification as filed. Additional discussion of the use of ports is provided with regard to the discussion of FIG. 11 and is found on pages 19-20.

With regard to the treatment of various diseases, the present application discusses the treatment of neurological disorders on pages 19. In addition, the present application has incorporated by reference several prior art patents that further discuss the treatment of various types of disorders and diseases, such as, for example, U.S. Patent No. 5,792,186 and U.S. Patent No. 5,711,316. To avoid adding unnecessary limitations, however, claim 86 has been amended and claims 87-88 have been cancelled. For the same reason, claim 107 has been amended and claims 108-109 have been cancelled.

Regarding the alleged lack of support for "determining liquid infusion rate through first and second catheters with a parameter and signal level" in claim 91, support at least is found in U.S. Patent No. 5,792,186, which is incorporated by reference into the current application. Regarding the alleged lack of support for "use of parameters and settings to control liquid infusion" in claims 92-98, support for this is at least provided in U.S. Patent No. 4,692,147

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which was incorporated by reference into the current application and discloses methods of controlling a pump. Regarding the alleged lack of support for "the sensor in the proximity of liquid delivery position" in claim 104, support is at least found in U.S. Patent No 5,792,186, which is incorporated by reference into the current application. As these U.S. Patents are incorporated by reference, no new matter has been added.

As the incorporation by reference of essential and non-essential subject matter from U.S. Patents is in accordance with the procedures provided for in the MPEP 608.01(p) (May, 2004 rev.), Applicants respectfully submit that the current application contains sufficient written description support to show the inventors had possession of the claimed invention at the time of filing. Therefore, withdrawal of this ground of rejection is respectfully requested.

Objection to the Specification – Lack of Antecedent Basis

The specification, while providing support for the term "setting," did not expressly use the term. While disagreeing that antecedent basis is needed for the term "setting," to advance prosecution of the present application, a paragraph on page 19 of the specification has been amended. Applicants believe this amendment satisfies the need for antecedent basis for the term "setting" and as a pump disclosed in U.S. Patent No. 4,692,147, which was incorporated by reference, includes this ability, this amendment does not add new matter.

Rejection Under 35 U.S.C §102(b) - Gillis

Claims 80-83, 85-89, 103 and 107-109 were rejected as anticipated by Gillis. While not addressing the issue of whether Gillis can be properly considered prior art for the present pending application (but reserving the right to do so), the rejection is respectfully traversed below.

Gillis is directed towards an implantable guide that can be used in connection with a drug delivery device. (Gillis, Abstract). FIGS. 4-6 of Gillis are provided below.

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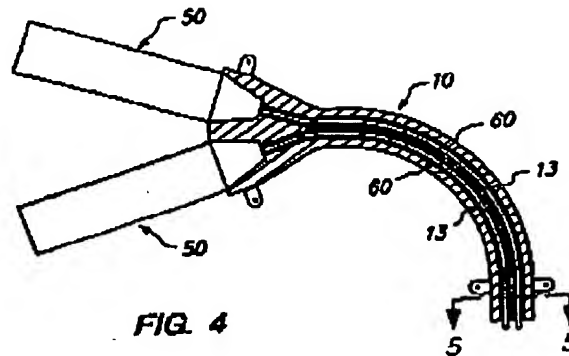


FIG. 4

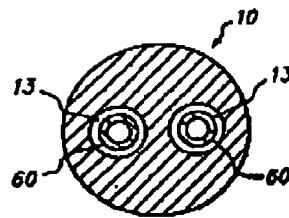


FIG. 5

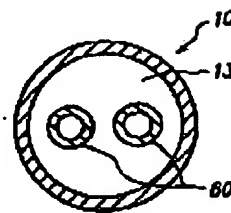


FIG. 6

As depicted in FIG. 4, Gillis discloses a guide 10 designed for use with two drug delivery devices 50. (Gillis, ¶ 86). Gillis explains that the guide may include a plurality of lumens 13 with a drug delivery catheter 60 positioned within the lumen 13. (Id.; see FIG. 5). As is apparent from FIGS. 4-6, however, the catheters 60 all have the same trajectory. Furthermore, Gillis does not direct the catheters 60 in an outwardly direction but rather directs them in a direction aligned with the guide 10 and the lumen 13.

Independent claim 80 recites the limitation "the lumen distal end having a plurality of openings, each opening capable of directing a catheter outwardly along a distinct predetermined trajectory." As noted above, Gillis does not disclose such a configuration. Therefore, as Gillis does not disclose all the limitations of claim 80, Gillis cannot fairly be said to anticipate claim 80.

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Independent claim 103 also recites the above limitation, therefore, Gillis cannot be said to anticipate claim 103 for the same reasons Gillis does not anticipate claim 80.

Claims 81 and 85-90 depend from claim 80 and necessarily include a least one limitation not disclosed by Gillis, therefore Gillis cannot fairly be said to anticipate claims 81 and 85-90.

Claims 107-109 depend from claim 103 and necessarily include at least one limitation not disclosed by Gillis, therefore Gillis cannot fairly be said to anticipate claims 107-109.

Accordingly, withdrawal of this ground of rejection is respectfully requested.

Rejection Under 35 U.S.C. § 103(a) – Howard & Elsberry

Claims 80, 81, 85-90, 103, and 107-109 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Howard. Claims 82-84, 91-102 and 104-106 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Howard in view of Elsberry. Thus, all the pending claims stand rejected under 35 U.S.C. § 103(a) in view of Howard, alone or in combination with Elsberry.

Howard discloses methods and apparatus for curbing the appetite of individuals suffering from morbid obesity. (Howard, Abstract). FIG. 30 of Howard is provided below.

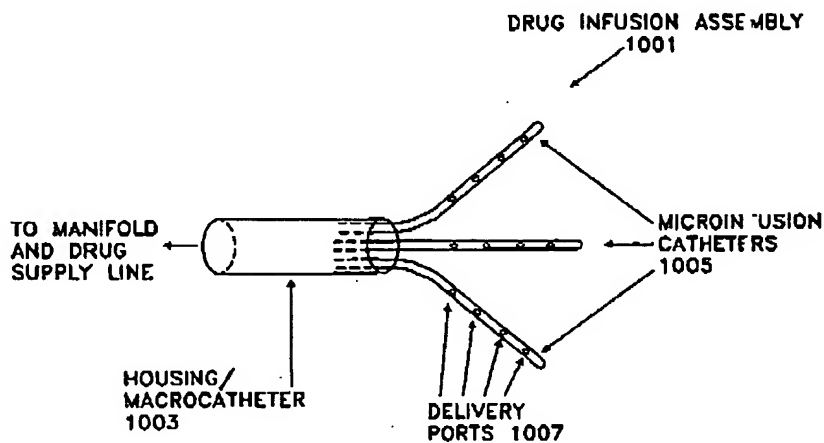


FIG. 30

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As can be readily appreciated, the macrocatheter 1003 has a single opening from which the catheters 1005 extend. While the catheters 1005 include delivery ports 1007, nothing extends from the delivery ports 1007. Thus, FIG. 30 of Howard completely fails to disclose "the lumen distal end having a plurality of openings, each opening capable of directing a catheter outwardly along a distinct predetermined trajectory."

FIG. 25 of Howard is depicted below:

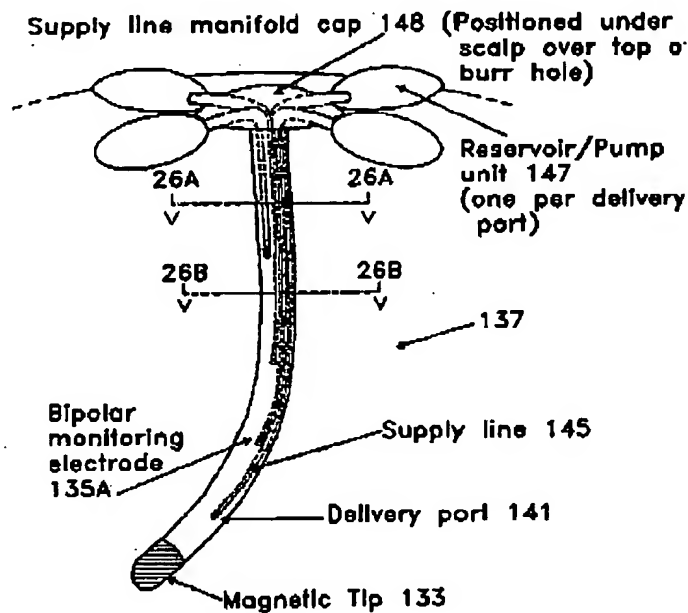


FIG. 25

As is apparent, the support shaft 137 includes a delivery port 141 on the side of the support shaft 137 for delivering a drug from a reservoir/pump 147 via a supply line 145. However, Howard does not disclose or suggest extending a catheter out of the delivery port 141. Indeed, the Applicants have been unable to locate anything in Howard that suggests such a modification would be possible. Thus, FIG. 25 and the supporting text do not disclose or suggest a "lumen distal end having a plurality of openings, each opening capable of directing a catheter outwardly along a distinct predetermined trajectory."

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Regarding Elsberry, the Office Action did not suggest Elsberry discloses a "lumen distal end having a plurality of openings, each opening capable of directing a catheter outwardly along a distinct predetermined trajectory." Therefore, the addition of Elsberry to Howard fails to correct the above noted deficiency. Accordingly, neither Howard nor Elsberry disclose the limitation of "lumen distal end having a plurality of openings, each opening capable of directing a catheter outwardly along a distinct predetermined trajectory." Therefore, the Office Action fails to establish a *prima facie* case of obviousness. See MPEP 706.02(j) ("To establish a *prima facie* case of obviousness, three basic criteria must be met. ... [Third], the prior art reference[s] ... must teach or suggest all the claim limitations").

While not addressing the above issue, the Office Action suggested that it would be obvious to modify the electrode support shaft 137 disclosed FIG. 25 in light of FIG. 100. As an initial matter, the Office Action has failed to provide any support for such a statement. Furthermore, the Applicants have been unable to locate anything in Howard that suggests modifying the supply line 145 of FIG. 25 to accept a catheter 1005 of FIG. 30, nor is there any reason to indicate such a modification would be successful. See MPEP 706.02(j) ("To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success."). Instead, the only suggestion to do so is found in the present application, suggesting the rejection is based on impermissible hindsight reconstruction.

The pending independent claims 80, 102 and 103 include the limitation "the lumen distal end having a plurality of openings, each opening capable of directing a catheter outwardly along a distinct predetermined trajectory." As noted above, Howard fails to disclose, suggest or teach such a configuration and the addition of Elsberry does not correct this deficiency. Therefore, Howard, alone or in combination with Elsberry, fails to disclose, suggest or teach all the limitations of the pending independent claims 80, 102 and 103. As Howard, alone or in combination with Elsberry fails to disclose all the limitations of claims 80, 102 and 103, the combination of Howard and Elsberry cannot be said to make claims 80, 102 and 103 obvious.

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The remaining pending claims 81-101 and 104-109 depend from claim 80 and claim 103, respectively and necessarily include at least one limitation not disclosed, suggested or taught by Howard, alone or in combination with Elsberry for the reasons discussed above with regard to the independent claims.

Accordingly, withdrawal of this ground of rejection for claims 80-109 is respectfully requested.

CONCLUSION

It is believed that no fee is required for this submission. If any fee is required or if an overpayment is made, the Commissioner is authorized to debit or credit our Deposit Account No. 19-0733, accordingly. All rejections having been addressed, the Applicant respectfully submits that the instant application is in condition for allowance, and earnestly solicits prompt notification of the same.

Respectfully submitted,

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Dated: June 21, 2005

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